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Group 1643

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PATENT

Docket No. 2710-4007 US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Michael B. CHANCELLOR and
Johnny HUARD Group Art Unit: 1643

Serial No. : 09/302,896 Examiner: Kashal

Filed : April 30, 1999

For : Muscle-Derived Cell Mediated Gene Delivery for Treating Muscle- or Bone-
Related Injury or Dysfunction

EXPRESS MAIL CERTIFICATE

Express Mail Label No. EL 513 414 614 US

Date of Deposit: May 1, 2000

I hereby certify that the following attached paper(s) and/or fee

1. Supplemental Information Disclosure Statement (3 sheets);
2. PTO Form 1449 listing 12 references (2 sheets);
3. Copies of 12 listed references;
4. Return Postcard

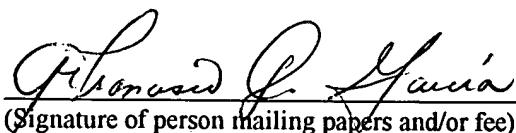
is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37

C.F.R. §1.10 on the date indicated above and is addressed to: **BOX: INFORMATION DISCLOSURE**

STATEMENT, Assistant Commissioner for Patents, Washington, D.C. 20231.

Francisco Garcia

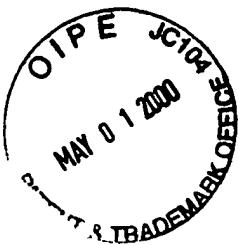
(Typed or printed name of person mailing papers and/or fee)


Francisco Garcia

(Signature of person mailing papers and/or fee)

CORRESPONDENCE ADDRESS:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, New York 10154
(212) 758-4800
(212) 751-6849 Facsimile



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For : MUSCLE-DERIVED CELL MEDIATED GENE DELIVERY FOR TREATING
MUSCLE- AND BONE-RELATED INJURY OR DYSFUNCTION

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

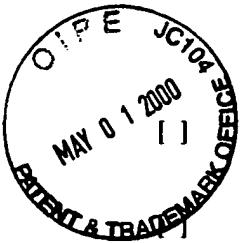
ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

This Supplemental Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:

2. For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. _____, filed _____.
4. No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:



37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application for filing date of the continued prosecution application filed on _____; or

37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or

37 C.F.R. §1.97(b)(3), before the mailing date of a first Office Action on the merits, whichever event occurred last.

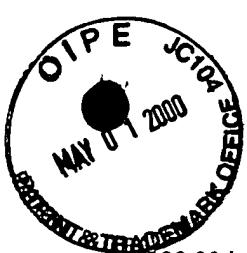
5. No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):

- A check in the amount of \$240.00 is enclosed in payment of the fee.
- Charge the fee to Deposit Account No. 13-4500. Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
 - a. one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. the attached petition requesting consideration of this Information Disclosure Statement; and
 - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
 - a. 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - b. 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To withdraw Application From Issue.
 - c. The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. I hereby certify that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after make reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.



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Docket No. 2710-4007US1

10. [] A check in the amount of \$130.00 is enclosed in payment of the fee due under C.F.R. §1.17(i)(1).

[] Charge the fee due under C.F.R. §1.17(i)(1) to Deposit Account No. 13-4500. Order No. 2710-4007US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

[X] The Assistant Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500. Order No. 2710-4007US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

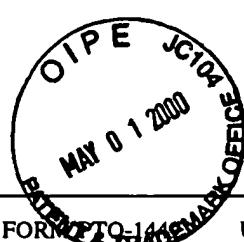
By: Leslie Serunian
Leslie A. Serunian
Registration No. 35,353

Dated: May 1, 2000

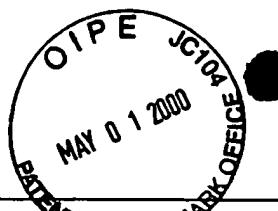
CORRESPONDENCE ADDRESS:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, New York 10154
(212) 758-4800
(212) 751-6849 Facsimile

FORM: IDS.NY
Rev. 05/26/98



U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				ATTY. DOCKET NO. 2710-4007 US1	SERIAL NO. 09/302,896		
				APPLICANT M. B. CHANCELLOR and J. HUARD			
				FILING DATE April 30, 1999	GROUP ART UNIT 1643		
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1	5,594,032	1/14/97	Gonzalez-Cadavid et al.	514	645	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
	2	WO 98/36055	20/8/98	PCT			YES NO
	3	WO 96/18303	20/6/86	PCT			
	4	WO 99/47163	23/9/99	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, Etc.)							
	5	M. Reza Dana et al., "Interleukin-1 Receptor Antagonist Suppresses Langerhans Cell Activity and Promotes Ocular Immune Privilege", <u>Investigative Ophthalmology & Visual Science</u> , 1998, 39:70-77.					
	6	G. Ferrari et al., "Muscle Regeneration by Bone Marrow-Derived Myogenic Progenitors", <u>Science</u> , 1998, 279:1528-1530.					
	7	E. Barr and J. Leiden, "Systemic Delivery of Recombinant Proteins by Genetically Modified Myoblasts", <u>Science</u> , 1991, 254:1507-1509.					
	8	T. Katagiri et al., "Bone Morphogenetic Protein-2 Converts the Differentiation Pathway of C2C12 Myoblasts into the Osteoblast Lineage", <u>J. Cell Biology</u> , 1994, 127:1755-1766.					
	9	T.A. Rando and H. Blau, "Primary Mouse Myoblast Purification, Characterization, and Transplantation for Cell-mediated Gene Therapy", <u>J. Cell Biology</u> , 1994, 125:1275-1287.					
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							



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FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Papers, Etc.)								
	10	T. Yokoyama et al., "Gene Therapy as a Potential Treatment for BPH; Injection of Myoblast-Adenovirus Transfected with Human Inductible Nitric Oxide Synthase (iNOS) into the Proximal Urethra", <u>J. Urology</u> , 1999, 161 (4) Supplement:305 (Abstract 1775).						
	11	J. Huard et al., "Myoblast Injection into the Bladder Wall: A Possible Method of Modulating Detrusor Contractility and Cell-Mediated Gene Therapy for Bladder Dysfunction", <u>J. Urology</u> , 1998, 159 (5) Supplement:16 (Abstract 62).						
	12	J. Huard et al., "Nitric Oxide Synthase (NOS) Gene Therapy for Erectile Dysfunction; Comparison Between Plasmid, Adenovirus and Adenovirus Transduced Myoblast Vectors", <u>J. Urology</u> , 1998, 159:90 (Abstract 342).						
EXAMINER					DATE CONSIDERED			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								